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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,312

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Kevin Wickline

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS

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EXAMINER

GUPTA, VANI

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/599,312	<b>Applicant(s)</b> WICKLINE ET AL.	
	<b>Examiner</b> VANI GUPTA	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-5 and 7-18 is/are allowed.
- 6) ☒ Claim(s) 1 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. ***Claims 2 – 5, 7, and 8 are objected to as being dependent upon a rejected base claim (Claim 1), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Or, if the Applicant so chooses, these limitations may instead be included in Claim 1, so that Claim 1 also would be allowable of prior art.***
2. ***Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim (Claim 1).***

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is noted that Claim 7 indicates “the non elastomeric thermoplastic” in line 2. However, Claim 1 only indicates “a high performance thermoplastic.” Claim 7, therefore, lack antecedent basis. Examiner notes, however, that Claim 2 (also dependent on Claim 1) indicates that the high performance thermoplastic of Claim 1 is a non elastomeric thermoplastic. Examiner requests Applicant to make the appropriate corrections to Claim 7.

### ***Inventorship***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. ***Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Silverstein et al. (US 5,178,150).***

***Regarding Claim 1***, Silverstein et al. discloses an ultrasonic probe comprising a transducer disposed at the distal end, wherein an ultrasound transducer (52) is enclosed within a fluid chamber/balloon (***flexible bag, 62***). Silverstein also discloses that the transducer is movably mounted within the fluid chamber. ***Figures 2 - 4*** depict an arrangement of the transducer within the fluid-chamber-balloon combination.

Applicant should note that the transducer being an array transducer is an inherent arrangement for imaging transducers of ultrasonic imaging devices.

The coupling fluid within the fluid-chamber/flexible-bag is acoustic fluid (*col. 3, lines 14 – 16*), and therefore, is inherently highly “transmissive” of ultrasound energy.

Furthermore, the fluid-chamber/flexible bag is a thin-walled compensation balloon in that it is compliant and can change shape, or expand. Since the fluid-chamber/flexible bag and thin-

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walled compensation balloon are the one and the same, the thin-walled compensation balloon is inherently in “communication” with the fluid chamber.

Furthermore, since Silverstein et al. do not discuss heating or cooling the acoustic fluid, the acoustic fluid is inherently at nominal, or room, temperature (*Abstract*).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. ***Claim 6 is rejected under 35 U.S.C. 103(a) as being obvious over Silverstein et al. (US 5,178,150).***

***Regarding Claim 6***, utilizing acoustic fluid that comprises silicone oil is an obvious design choice because one of ordinary skill in the art would be aware that acoustic fluid that comprises oil-based components that would provide lubrication to the transducer components, therefore optimizing performance of the rotational transducer of Silverstein et al.

### ***Allowable Subject Matter***

1. ***Claims 2 and 7 are allowed.***

The following is a statement of reasons for the indication of allowable subject matter: prior art neither teaches nor suggests a catheter that comprises a thin-walled volume compensation balloon that is formed of a non elastomeric thermoplastic material. That is,

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relevant prior art does not reasonably suggest that an ultrasound transducer or probe may comprise a “volume compensation” balloon that contains liquid and does not change in shape as a balloon made of an elastomeric thermoplastic material may.

Applicant should note that Claim 1 is still rejected because this feature is not actually recited in Claim 1. Please refer to the rejection above, and response to applicants’ arguments below for further details.

**2.     *Claims 3 – 5 are allowed.***

The following is a statement of reasons for the indication of allowable subject matter: these claims depend on Claim 2.

**3.     *Claim 8 is allowed.***

The following is a statement of reasons for the indication of allowable subject matter: these claims depend on Claim 7.

**4.     *Claim 9 is allowed.***

The following is a statement of reasons for the indication of allowable subject matter: the prior art neither teaches nor suggests “the thin-walled balloon of the ultrasonic probe exhibits a high compliance of less than 2 psi per ml; a low permeation rate to acoustic fluid of less than 1.0; a high burst strength in excess of 10 atmospheres; *and* a thermal stability which does not significantly decrease compliance at low temperatures of operation”.

**5.     *Claim 10 is allowed.***

The following is a statement of reasons for the indication of allowable subject matter: prior art neither teaches nor suggests a catheter that comprises a volume compensation balloon that is formed of a substantially *non elastic* material and contains acoustic fluid.

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**6. *Claims 11 – 18 are allowed.***

The following is a statement of reasons for the indication of allowable subject matter: these claims depend on Claim 10.

***Response to Arguments***

**1. *Applicant's arguments filed June 30, 2009 with respect to claims 1 and 6 have been fully considered but they are not persuasive.***

Applicant argues that Silverstein et al. (US 5,178,150) lacks virtually all of the characteristics of the volume compensation balloon recited in the present Claim 1. Examiner respectfully disagrees and directs Applicant to passages in column 8, lines 26 – 31, wherein the bag can conform to irregular shapes brought on by pressure of fluid. Therefore, it is capable of acting as a volume compensation balloon. Additionally, in response to Applicant's arguments about not "containing a small fraction of fluid of the fluid chamber," but rather all of the fluid of the fluid chamber, Examiner first points out that the claim language is not very specific as to what is considered a "small fraction." Additionally, since the claim language also indicates that the balloon is "communication with the fluid chamber," one skilled in the art could interpret this as the balloon being connected to fluid chamber in such way that the two are practically the one and the same. Therefore, the fluid could be in any one of the two components, or in both, at the same time.

With respect to the type of material used to form the balloon, Applicant should note that the features upon which applicant relies upon: i.e., (1) high performance thermoplastic material is a non-elastomeric material; and (2) balloon being contained in a very small space in the probe

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are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As is known in the art, thermoplastic is a type of polymer, and many polymers are elastomeric. The fact that the volume compensation balloon is made of a high performance thermoplastic balloon such that “at room temperature the volume compensation balloon is limp with only a small fraction of the fluid of the fluid chamber for which it provides volume compensation; and when the temperature of the probe increases the balloon will begin to fill with fluid to compensate for expansion of the fluid in the transducer chamber” can be included in determination of patentability because it is not recited in Claim 1.

Therefore, Silverstein et al. still reads on claims 1 and 6.

**7. *Applicant’s arguments on page 9 of Remarks, with respect to claims 2 – 8 and 10 – 18 have been fully considered and are persuasive. The rejections of these claims have been withdrawn.***

However, Examiner will address aspects of Silverstein et al. that are applicable to these claims for sake of prosecution.

Applicant argues that “it is not apparent that Silverstein et al. use an array transducer; they only say that they have an “ultrasound transducer 52.” Examiner points out that Silberstein et al. discusses generating two-dimensional images (col. 4, ll. 61 – 66), and therefore would require at least a linear array transducer.

Applicant also argues that Silverstein et al. also does not have drive mechanism to move the array during scanning. Instead, an actuating member 90 is manipulated manually to



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reciprocate the transducer for linear or rotational scanning as stated in column 7, lines 44 – 57.

Examiner respectfully disagrees that the actuator is not a drive mechanism. The actuator, as Claim 10 requires, moves the array transducer during scanning. Whether the movement is accomplished manually or automatically has no affect. See *In re Venner*, 120 USPQ 192.

Applicant's arguments about the bag **(62)** not being “substantially *non elastic*” are persuasive. See discussion under Allowable Subject Matter.

Applicant's arguments with respect to *Lenz (US Pat. 7,479,128)* are persuasive.

### ***Conclusion***

**1. *The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.***

- a. Lenker (US 6,592,526 B1) suggests a catheter balloon may be made of high performance thermoplastic such as polyethylene terephthalate (PET), polyimide or other high-strength polymers (col. 7, ll. 21 – 35). Figure 3 suggests that the balloon may be partially expanded at room temperature. Lenker does not suggest that the balloon is in fluidic communication with the fluid chamber **(204)**; or that it contains acoustic fluid.
- b. Jang et al. (US 5,117,831) for dilation balloon made of thermoplastic such as polyethylene, polyvinyl chloride, polyethylene terephthalate, etc. that limits maximum inflation (Abstract; col. 5, ll. 17 - 34).

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**2. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./

Examiner, Art Unit 3768

/Long V Le/

Supervisory Patent Examiner, Art Unit 3768